

## **REMARKS/ARGUMENTS**

Applicant(s) and applicant's attorney express appreciation to the Examiner for the courtesies extended during the recent telephonic interview held on September 29, 2003. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-18 20-21 and 23-25 are pending, wherein claims 1, 7, 10-12, 17-18 and 20-21 were amended, claims 19 and 22 were cancelled, and claims 23-25 were added.

### **I. OVERVIEW OF THE INVENTION**

The present application discloses various embodiments of an interference screw that can be used to secure a soft tissue graft within a bone tunnel. As discussed in paragraphs 15, 55 and 56 of the specification, an important feature of the present invention is the ability of the inference screw to exert a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel and lower compressive force in the cancellous bone region. That is because the optimal compressive force that can be applied to a tissue graft in the cortical region is greater than the optimal compressive force that should be applied to the tissue graft in the cancellous bone region.

Cortical bone is located at the bone surface and is much harder than cancellous bone located beneath the cortical bone in the interior of the bone. When an inference screw according to the invention is threadably inserted into a bone tunnel to secure a soft tissue graft (*i.e.*, by pressing the soft tissue graft against the bone tunnel wall), a proximal threaded section of the interference screw presses the soft tissue graft against cortical bone and a distal threaded section of the interference screw presses the soft tissue graft against cancellous bone. Because the proximal threaded section has an average diameter that is greater than the diameter of the distal threaded section, the proximal threaded section exerts a greater compressive force against the soft tissue graft in the cortical bone region, and the distal threaded section exerts a smaller compressive force against the soft tissue graft in the cancellous bone region.

The end result is a stronger initial soft tissue graft attachment as a result of exerting a greater compressive force against the soft tissue graft in the much harder cortical bone region, and a stronger final graft attachment as a result of exerting a smaller compressive force against the soft tissue graft in the softer, more vital cancellous bone region. Applying the same compressive force against the soft tissue graft in both the softer and more vital cancellous bone

region and the harder cortical bone region can cause one of two results: (1) if the force applied in the cortical bone region is less than optimal, the strength of the initial tissue graft attachment is less than optimal or (2) if the force applied in the cancellous bone region is greater than optimal, damage or weakening of the long-term tissue growth between the cancellous bone and soft tissue graft can occur.

As will be shown below, none of the cited references teaches or suggests an interference screw or method that results in greater force being applied to a soft tissue graft in the cortical bone region and less force being applied to the graft in the cancellous bone region.

## **II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Office Action rejects claim 22 under 35 U.S.C. § 112, second paragraph, on the grounds that it omits essential steps. In response, Applicant have cancelled claim 22 and replaced it with new method claim 25 in an attempt to overcome this rejection.

## **III. REJECTIONS UNDER 35 U.S.C §§ 102 AND 103**

The Office Action rejects claims 1-7, 11-13 and 17-21 under U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,387,129 (Rieser et al.)<sup>1</sup> and claim 22 under U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,234,430 (Huebner '430). The Office action further rejects claims 8, 9 and 14-16 under U.S.C. § 103(a) as being obvious over Rieser et al. and claim 10 as being obvious over Rieser et al. in view of Huebner '430. The Examiner also mentioned U.S. Patent No. 6,030,162 (Huebner '162) as being potentially relevant during the Examiner Interview. Applicant will now show why the claims as amended and newly presented are patentable over the cited art.

### **A. Claim 1**

Claim 1 was amended to specify that the distal threaded section has "a constant diameter". Support for this limitation is found in paragraphs 35 and 59 of the specification. The constant diameter of the distal threaded section causes the interference screw to exert a constant compressive force against a soft tissue graft in the cancellous bone region of a bone tunnel along

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<sup>1</sup> Because Rieser et al. is only citable under U.S.C. § 102(e), Applicant does not admit that Rieser et al. is in fact prior art but reserves the right to "swear behind" it at some future time in order to remove it as a reference.

the entire length of the distal threaded section when in use. The larger average diameter of the proximal threaded portion causes the interference screw to exert a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel when in use.

Claim 1 was also amended to claim "proximal and distal threads having the same pitch". Support for this limitation is found in paragraphs 21, 39 and 47 of the specification. These paragraphs teach that the proximal and distal threads can have the same or different pitch but that varying the pitch is less preferred, which means that having the same pitch is more preferred.

Rieser et al. and Huebner neither teach nor suggest an interference screw having the features recited in amended claim 1. Rieser et al. discloses a proximal tibial interference screw 2, a distal tibial interference screw 20, and a femoral interference screw, each of which includes a larger portion having a constant diameter and smaller tapered portion at the end. *See* Figures 1, 3 and 5. Huebner '430 discloses a screw that is substantially identical to the Rieser et al. screw. *See* Figure 1 and 3. If the portion having constant diameter is taken to correspond to the "proximal threaded portion" of claim 1, the Rieser et al. and Huebner '430 screws would then lack structure corresponding to the "distal threaded portion" having "a constant diameter that is less than the average diameter of the proximal threaded portion". Conversely, if the portion having constant diameter is taken to correspond to the "distal threaded portion" of claim 1, the Rieser et al. and Huebner '430 screws would then lack structure corresponding to the "proximal threaded portion", which has a larger average diameter than the constant diameter distal threaded portion."

During the telephonic interview, the Examiner brought up Huebner '162. In response, Applicant points out that Huebner '162 is directed to "a screw adapted to create axial tension along its length" that is specifically designed to bring two pieces of a broken bone together. Col. 1, lines 5-6; *see* Figures 8 and 9. Because the purpose of the Huebner '162 screw is to draw two pieces of a broken bone together, as shown in Figures 8 and 9, the leading end 18 and trailing end 20 have threads (*e.g.*, screw thread 22) of varying pitch. Col. 3, lines 37-45.

In a typical screw, the pitch in the trailing section would be between 10 and 90 percent of the pitch in the leading section, with a pitch change around 50 percent, for example, being a typical value in orthopedic applications. It should be understood that greater or lesser pitch changes may be effective depending on the compression and reduction required for any particular application. In orthopedic applications, the pitch would typically fall in the range of between 10 and 100 thousandths of an inch.

Col. 5, lines 33-41.

In contrast to the bone repair screw of Huebner '162, the threads in the proximal and distal threaded sections of the interference screw of claim 1 have "the same pitch". It would be contrary to Huebner '162 to provide a screw in which the proximal and distal threaded sections have "the same pitch" because it would impede the ability of the Huebner '162 screw to properly bring two pieces of a broken bone together.

Moreover, one of skill in the art would not have been motivated to combine the teachings of Rieser et al. or Huebner '430 with Huebner '162. The Rieser et al. screw is designed to affix a soft tissue graft within a bone tunnel and appears to have a thread of continuous pitch. The Huebner '430 screw is designed to affix a bone graft within a bone tunnel and also appears to have a thread of continuous pitch. Because it is critical to the operation of the Huebner '162 screw to having varying thread pitch (*i.e.*, "to create axial tension along its length"), there would have been no motivation to combine Huebner '162 with either Rieser et al. or Huebner '430 for any reason, let alone to obtain the interference screw of claim 1.

In view of the foregoing, Applicant submits that claim 1 is neither anticipated by nor obvious over any one of Rieser et al., Huebner '430 or Huebner '162, either alone or in combination with any other art of record.

**B. Claims 2-16 and 23**

Because dependent claims 2-16 and 23 depend from claim 1, they are patentable for at least those reasons for why claim 1 is patentable over the prior art of record. They also include additional limitations that, when taken in combination with the limitations of claim 1, further distinguish over the prior art. Support for new claim 23 is found in paragraph 50 of the specification.

Some of dependent claims 2-16 and 23 were amended to maintain proper antecedent basis and/or to delete extraneous claim language.

**C. Claim 17**

Amended claim 17 alternatively claims an interference screw that includes a proximal threaded section, a distal threaded section having a constant diameter that is less than the average diameter of the proximal threaded section, a single continuous thread of uniform pitch extending

between the proximal and distal ends, and a tapered section disposed between the distal threaded section and the distal end that facilitates insertion of the distal end of the interference screw into a bone tunnel. As discussed above, Rieser et al. and Huebner '430 neither teach nor suggest an interference screw having a proximal threaded section and a distal threaded section having a constant diameter that is less than the average diameter of the proximal threaded section. Moreover, because claim 17 further requires "a tapered section disposed between the distal threaded section and the distal end", it would be even more difficult to find analogous structure in the Rieser et al. and Huebner '430 screws.

As also discussed above, an important feature of the bone repair screw of Huebner '162 is that the leading and trailing sections of the bone repair screw having varying pitch in order "to create axial tension along its length". Col. 1, lines 5-6; col. 5, lines 33-41. In contrast to Huebner '162, the interference screw of claim 17 comprises "a single continuous thread of uniform pitch extending between the proximal and distal ends".

Finally, there would have been no motivation to combine the features of the bone repair screw disclosed in Huebner '162 with the features of the soft tissue graft fixation screw of Rieser et al. or the bone graft fixation Huebner '430.

**D. Claims 18 and 20**

Because dependent claims 18 and 20 depend from claim 17, they are patentable for at least those reasons for why claim 17 is patentable over the prior art of record. They also include additional limitations that, when taken in combination with the limitations of claim 17, further distinguish over the prior art.

Dependent claims 18 and 20 were amended to maintain proper antecedent basis and/or to delete extraneous claim language.

**E. Claim 21**

Amended claim 21 alternatively claims an interference screw that includes a proximal threaded section, a distal threaded section having a constant diameter that is less than the average diameter of the proximal threaded section, and a single continuous thread of uniform pitch extending between the proximal and distal ends. Rieser et al. and Huebner '430 clearly do not

disclose or suggest an interference screw having a distal threaded section of constant diameter, and Huebner '162 does not disclose or suggest an interference screw having "a single continuous thread of continuous pitch".

**F. Claim 24**

Claim 24 was added to recite an interference screw having a proximal threaded section, a distal threaded section of constant diameter, a transition section having increasing diameter from the distal threaded section to the proximal threaded section, and a tapered end. Support for this new claim is found in Figure 2 and original claims 3-5. None of the cited art teaches or suggests the combination of features recited in new claim 25. Rieser et al. and Huebner '430 do not disclose or suggest an interference screw having a distal threaded section of constant diameter. Huebner '162 does not disclose or suggest a screw that includes a transition section having increasing diameter from the distal threaded section to the proximal threaded section.

**G. Claim 25**

New claim 25 was added to claim, for the first time, a method of securing a soft tissue graft to a bone comprising specific acts disclosed in the specification. Support for new claim 25 is found in paragraphs 15, 55 and 56, as well as the originally filed claims. None of Rieser et al., Huebner '430 or Huebner '162 teach or suggest the method of claim 25. Rieser et al. discloses "bicortical tibial fixation of anterior cruciate ligament grafts". Col. 1, lines 14-15. Bicortical tibial fixation of an ACL graft, by definition, requires the insertion of two interference screws (or fixation devices) into the tibial bone tunnel:

The present invention overcomes the disadvantages of the prior art and achieves the foregoing objectives by providing apparatus and methods for bicortical fixation of ligament grafts, whereby the graft is fixed at two cortical locations ("bicortical") within the tibial tunnel using a pair of fixations devices.

Col. 1, lines 49-54 (emphasis added); *see also* col. 3, line 53 – col. 4, line 18; col. 5, lines 8-22; claim 1. "The proximal tibial screw is preferably between about 10-25 mm in length, while the distal tibial screw is about 10-20 mm long overall." Col. 5, lines 2-4.

In contrast to the foregoing, claim 25 recites a method of attaching a soft tissue graft to a bone that includes "threadably inserting a single interference screw having a length in a range of

about 35 mm to about 40 mm” (emphasis added). Rieser et al. neither teaches nor suggests a method of securing a soft tissue graft to a bone using “a single interference screw” but rather “bicortical fixation” which requires “a pair of fixation devices”. Col. 1, lines 49-54. Moreover, Rieser et al. neither teaches nor suggests an interference screw “a having a length in a range of about 35 mm to about 40 mm”. Instead, the two screws of Rieser et al. have lengths of about 10-25 and 10-20 mm, respectively, and it is unlikely that two interference screws of the length required in claim 25 would be able to fit within the tibial bone tunnel formed in Rieser et al.

Huebner '430, on the other hand, discloses a method for securing a “bone graft” within a bone tunnel. Col. 1, lines 6-9 and 52-54; col. 2, lines 16-18. A bone graft is hard tissue. In contrast, claim 25 is directed to a method of securing “a soft tissue graft to a bone”. Nor does the method of Huebner '430 inherently result in “a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel compared to the compressive force applied to the soft tissue graft in the cancellous bone region”, as required by claim 25.


Finally, Huebner '162 neither teaches nor suggests a method of attaching a tissue graft of any kind to a bone, let alone in the manner recited in claim 25.

#### IV. CONCLUSION

In view of the foregoing, Applicant believes that the claims are presently in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application, may be clarified through a telephone interview or that can be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 29<sup>th</sup> day of September 2003.

Respectfully submitted,



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